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510(k) Summary

Submitted By: Thomas J. Kardos, Vice President Regulatory Affairs
Cook Vascular Incorporated
Route 66, River Road
Leechburg, PA 15656
724-845-8621

April 5, 2001

Names of Device:

Trade Name:	Electrosurgical Dissection Sheath and Interface Adaptor
Common/Usual Name:	Dilator catheter
Classification Name:	Vessel dilator for percutaneous catheterization 21 CFR 870.1310 (74DRE); Class II

Predicate Devices:

Cook Vascular Inc.	Byrd Dilator Sheath Set - Teflon	(D.C.# K902469, 74DRE)
Maxim Medical, Inc.	Vessel dilator	(D.C.# K963388. 74DRE)

Device Description:
The Cook Vascular Electrosurgical Dissection Sheath is a teflon mechanical dilating sheath incorporating a pair of tungsten electrodes at the distal tip of the sheath. The electrodes are connected to a standard electrosurgical generator by way of the accessory Electrosurgical Dissection System Interface Adaptor, allowing the device to augment mechanical dilation with electrosurgical point dissection at the electrodes as needed.

Intended Use:
The Cook Vascular Electrosurgical Dissection Sheath is intended for use in patients requiring the percutaneous dilation and dissection of tissue surrounding pacemaker and defibrillator leads. It is supplied sterile for one-time use.

Substantial Equivalence:
The Cook Vascular Electrosurgical Dissection Sheath is comparable to the predicate Byrd Teflon sheath with respect to intended use. Clinical testing provides evidence of equivalent clinical outcomes with the new technological characteristic of electrosurgery.

Discussion of Tests and Test Results:
The Cook Vascular Electrosurgical Dissection Sheath underwent non-clinical electrical, temperature, mechanical, shelf-life, and biocompatibility testing, as well as *in vivo* safety testing and clinical safety and effectiveness testing.

Conclusions Drawn from Tests:
Being similar to predicate devices with respect to intended use and technology, the Cook Vascular Electrosurgical Dissection Sheath meets the requirements for 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

Mr. Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular, Inc.
P.O. Box 529, Route 66 River Road
Leechburg, PA 15656

Re: K010055
Trade Name: Electrosurgical Dissection Sheath
Regulation Number: 870.1310
Regulatory Class: II (two)
Product Code: DRE
Dated: April 5, 2001
Received: April 9, 2001

Dear Mr. Kardos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

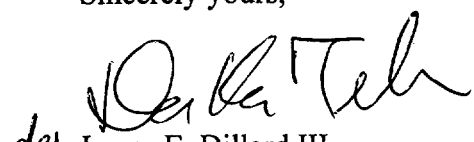
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010055

Device Name: Cook Vascular Electrosurgical Dissection Sheath

Indications For Use: The Cook Vascular Electrosurgical Dissection Sheath is intended for use in patients requiring the percutaneous dilation and dissection of tissue surrounding pacemaker and defibrillator leads. It is supplied sterile for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010055

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)